Improving Rates of the Birth Dose of Hepatitis B Vaccination in the Newborn Nursery: A QI Project

**How to address vaccine hesitancy and refusal:** One way to open a parent-focused dialogue is by candidly asking, “I noticed your baby hasn’t yet received the hepatitis B vaccine. What questions about the vaccine or hepatitis B infection do you have?” Having parents verbalize their questions and concerns, followed by a focused response to those concerns, can be an effective communication strategy. If the parents respond that they don’t want the vaccine or that they want to wait for the first PMD visit, one possible response is, “Since national guidelines recommend vaccination before hospital discharge, I want to address your concerns about giving the vaccine in the hospital. What are those concerns?” After you’ve entered a dialogue with the parents, you can focus your response to their specific questions using this FAQ hand-out as a guide.

*Hepatitis B Vaccine FAQs*

**What is Hepatitis B?**

Hepatitis B virus (HBV) can cause infection with lifelong, chronic illness resulting in scarring of the liver (cirrhosis) with liver cancer, or liver failure and death. The likelihood of developing chronic HBV increases when children are infected early in life. For example, about 90% of infants less than 1 year of age and about 30-50% of children infected between ages 1 and 5 years develop a chronic infection.

**How is Hepatitis B transmitted?**

HBV is most commonly spread by blood from infected people. The virus is most commonly transmitted by infected mothers to their babies during birth (one-third of cases), sex with an infected partner, sharing injection drug equipment, and contact with blood or sores of an infected person. Every year some people are infected without ever knowing where or by whom they were exposed to this virus. Therefore, vaccinating infants immediately after birth protects them during all periods of risk.

**How contagious is Hepatitis B?**

HBV is very contagious because of the large quantities of the virus in the blood during infection. It is more contagious than HIV. In fact, a teaspoon of blood from a person infected with HBV can contain as many as 5 billion infectious virus particles. This means that exposure to even tiny amounts of blood not visible to the naked eye can infect an individual. HBV is very stable and can remain viable for up to seven days on common household objects and public surfaces.

**What is the purpose of the birth dose if I tested negative for Hepatitis B during prenatal screening?**

Despite screening for HBV during pregnancy, infants still became infected by their mothers during birth before universal HBV vaccination. The reasons for this were incomplete tests, results were wrong, or exposure to the virus occurred after the test but before delivery. In addition, 50% of children with HBV became infected by someone other than their mothers during birth such as a household contact with HBV. Even if the parents believe no one in the household has HBV, infants and children have plenty of regular contact with people whose health status is confidential and unknown to parents. Babies can be infected with the virus soon after birth due to these potential exposures. Therefore, the best way to protect all children is through universal newborn vaccination.

Per the CDC, parents should not be encouraged to wait until the first PMD visit to have their newborn vaccinated. This misses an opportunity to protect the infant from an important period of risk, which is immediately after birth when transmission of HBV is most likely to occur from mothers who were missed during prenatal screening.

Of note, there has been a rise in acute HBV infection in the United States due to the opioid epidemic and rates of injection drug use, which is particularly high in Suffolk County. This increases the risk of perinatal transmission and chronic HBV infection in the newborn.

**How is the Hepatitis B vaccine made?**

The HBV vaccine is made by isolating the gene that makes the surface protein of the virus and inserting it into yeast cells. As the yeast cells replicate in the lab, they also produce the HBV surface protein. The newly produced surface proteins are purified from the other parts of the yeast cells to make the vaccine.

**What are the ingredients in the Hepatitis B vaccine?**

Apart from the active ingredient (the HBV antigen), HBV vaccines contain very small amounts of aluminum to strengthen the immune response to the vaccine. HBV vaccines may also contain trace amounts of other products used during the manufacturing process to grow the virus in culture, inactivate live virus, and preserve the vaccine product.

Engerix-B (which is what we usually administer in our nursery) contains aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate.

Recombivax contains formaldehyde, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, and yeast protein.

**Is the Hepatitis B vaccine safe?**

The HBV vaccine is very safe. The most common side effect is pain or soreness at the injection site. A causal link between HBV vaccination and reported side effects such as arthritis, multiple sclerosis, Guillain-Barré syndrome, neuritis, thrombocytopenia, optic neuritis, or transverse myelitis has never been established. In addition, no studies have shown any neurotoxic effects from the aluminum adjuvant that is used in the vaccine. The amount of aluminum contained in the vaccine is equivalent to amounts contained in breastmilk and formula.

**How the CDC monitors hepatitis B vaccine safety:**

The CDC and FDA continuously monitor the safety of vaccines after they are approved.  The CDC uses three systems to monitor vaccine safety: The Vaccine Adverse Event Reporting System (VAERS) enables anyone to report possible vaccine side effects regardless of causality. The Vaccine Safety Datalink (VSD) enables the CDC to continually monitor vaccine-related data. The Clinical Immunization Safety Assessment (CISA) conducts research on vaccine-associated health risks.

**Safety data of hepatitis B vaccine in infants:**

* In the early 1990’s, CDC conducted a study of healthy, full-term newborns to determine whether Hepatitis B vaccination of newborns increases the risk of fever or suspected sepsis.   The study found no evidence that newborn Hepatitis B vaccination is linked with any increase in fevers, sepsis evaluations, allergy, or central nervous system problems.
* In a large 4-year case series review of Hepatitis B vaccine reports among newborns, there were no serious health problems linked to the Hepatitis B vaccine.

**How effective is Hepatitis B vaccination?**

The birth dose of HBV vaccine is 75% effective in preventing perinatal HBV transmission from untreated mothers with HBV. In infants not exposed to maternal HBV at birth, vaccination produces seroprotection in 98% of healthy term infants. After a usual three-dose HBV vaccination series, approximately 90% (range: 74–100%) of people who receive the vaccine remain protected for at least 30 years regardless of the anti-HBs antibody titer. We don’t have data about immunity beyond 30 years, but most immunocompetent individuals likely remain protected for life.

References:

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Hepatitis B Vaccine Safety: <https://www.cdc.gov/vaccinesafety/vaccines/hepatitis-b-vaccine.html>

Hepatitis B Vaccine: <https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-details/vaccine-hepatitis-b-vaccine>

Injection Drug Use and Hepatitis B: <https://www.hhs.gov/hepatitis/blog/2018/02/21/the-rise-in-acute-hepatitis-b-infection-in-the-us.html>

Preventing Hepatitis B Transmission – Advisory Committee on Immunization Practices: <https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm>

Vaccine Excipient Summary (CDC): <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf>

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